GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1747
ANSWERED ON:28.11.2007
CLINICAL TRIALS BY MULTINATIONAL COMPANIES
Chaure Shri Bapu Hari;Dhotre Shri Sanjay Shamrao;Gawali Smt. Bhavana Pundlikrao

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Multi-National Companies are conducting clinical trials of certain medicines on Indian patients without the consent of patients and without the approval of Competent Authority;

(b) if so, the details thereof;

(c) whether the Government has conducted any inquiry to ascertain the facts in this regard;

(d) if so, the outcome thereof; and

(e) the total number of new drugs and formulations tested by the Multi-National Pharma Companies on Indian patients during the last three years and the impact thereof on the health of such patients?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) No such instances have been reported so far, that multinational companies are conducting clinical trials of certain medicines on Indian patients without the consent of patients and without the approval of competent authority.

(b) to (d) Question does not arise.

(e) The total number of Clinical trial permissions of new drugs and formulations granted to the multinational pharma companies in Indian patients during the last three years are as follows:-

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Year 2005  - 180
Year 2006  - 259
Year 2007(upto Oct) - 190
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No such instances have been reported so far, where these clinical trials have adversely affected the health of patients. Clinical trials are required to be conducted as per Good Clinical Practices, Schedule-Y of Drugs and Cosmetics Rules. Clearance from Ethical Committee is also required before conduct of such trials to safeguard the rights, safety and well-being of the trial subjects.